

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1, 3, 4, and 13 are currently pending and are directed to a method for the therapeutic treatment of a carcinoma in a mammal.

*The Amendments to the Claims*

Claim 1 has been amended to recite that the inhibitor of the mutated FGFR-4 is selected from the group consisting of a low molecular weight substance, an anti-FGFR-4 antibody, and a kinase inactive FGFR-4. Claim 4 has been amended to recite that the inhibitor is a kinase inactive FGFR-4. These amendments are supported by the specification at, e.g., page 4, lines 20-22. Accordingly, no new matter has been added by way of these amendments.

*The Office Action*

The Office Action rejects claims 1, 3, 4, and 13 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement and written description. Reconsideration of these rejections is hereby requested.

*Discussion of Rejections Under 35 U.S.C. § 112, First Paragraph*

The Office Action has rejected claims 1, 3, 4, and 13 under Section 112, first paragraph, as allegedly lacking enablement. This rejection is traversed for the reasons set forth below.

The Office Action contends that the specification enables the claimed method wherein the inhibitor of the mutated FGFR-4 is a kinase-inactive FGFR-4. However, the specification allegedly does not enable the use of *any* kinase-inactive receptor as an inhibitor of a mutated FGFR-4 protein according to the method of claim 1. Solely in an effort to advance prosecution of the present application, and not in acquiescence of the rejection, claims 1 and 4 have been amended to specify that the inhibitor of a mutated FGFR-4 protein is selected from the group consisting of a low molecular weight substance, an anti-FGFR-4 antibody,

and a kinase inactive FGFR-4. Accordingly, the enablement rejection under Section 112, first paragraph, should be withdrawn.

*Discussion of Written Description Rejection*

The Office Action has rejected claims 1, 3, 4, and 13 under Section 112, first paragraph, as allegedly lacking written description. This rejection is traversed for the reasons set forth below.

The Office Action alleges that, while the specification adequately discloses certain inhibitors of mutated FGFR-4 (i.e., kinase-inactive FGFR-4 and antibodies directed against the FGFR-4 receptor), the specification does not disclose a representative number of species of inhibitors of FGFR-4. Applicants note that claim 1 has been amended to recite that the inhibitor of the mutated FGFR-4 is selected from the group consisting of a low molecular weight substance, an anti-FGFR-4 antibody, and a kinase inactive FGFR-4. Because the Office Action acknowledges that the written description requirement has been satisfied with respect to a kinase-inactive FGFR-4 and an anti-FGFR-4 antibody, the written description rejection will be addressed as it relates to a low molecular weight substance.

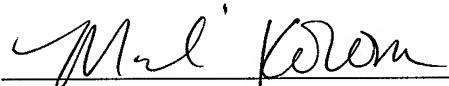
In reply to the previous Office Action, Applicants provided several references which demonstrated that receptor tyrosine kinase (RTK) inhibitors, or screening methods for identifying same, were known at the time the present application was filed, and could be used in connection with the claimed invention. In particular, small molecule inhibitors of FGFR, or methods for screening for such inhibitors, are disclosed in Dahrting et al., *J. Pharmacol. Exp. Ther.*, 281: 1446-1456 (1997), Hamby et al., *J. Med. Chem.*, 40: 2296-2303 (1997), Panek et al., *J. Pharmacol. Exp. Ther.*, 283: 1433-1444 (1997), Batley et al., *Life Sciences*, 62: 143-150 (1998), and Showalter et al., *Pharmacol. Ther.*, 76: 55-71 (1997). None of these references discloses inhibition of FGFR-4 *per se* (as noted in the Office Action), because it was not appreciated that FGFR-4 was a target for cancer therapy. Nevertheless, one of ordinary skill in the art would understand that, based on the structural similarities between the four members of the FGFR family, FGFR inhibitors disclosed in the prior art also would inhibit FGFR-4.

Accordingly, the subject matter of claim 1, as well as the claims depending therefrom, is described in the specification so as to reasonably convey to one of ordinary skill in the art the inventors had possession of the claimed invention. Thus, the written description under Section 112, first paragraph, is improper and should be withdrawn.

*Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



Melissa E. Kolom, Reg. No. 51,860  
LEYDIG, VOIT & MAYER, LTD.  
Two Prudential Plaza, Suite 4900  
180 North Stetson Avenue  
Chicago, Illinois 60601-6731  
(312) 616-5600 (telephone)  
(312) 616-5700 (facsimile)

Date: May 9, 2008